DIAZYME

JUL 2 1 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is k060619.

Submitter's name:	Diazyme Laboratories
Submitter's address:	3550 General Atomics Court San Diego, CA 92121
Phone:	858-455-4761
Fax:	858-455-4750
Name of Contact Person:	Roland Strickland Diazyme Laboratories 3550 General Atomics Court San Diego, CA 92121 Phone: 858-455-4761 Fax: 858-455-4750
Date the summary was prepared:	February 23, 2006
Name of the device:	In Vitro Bicarbonate/Carbon Dioxide Test System
Trade Name:	Diazyme Carbon Dioxide Enzymatic Assay
Common/Usual Name:	Bicarbonate/Carbon Dioxide Test System
Classification Name:	Enzymatic, Carbon-Dioxide
Device Class	II
Predicate Device:	The legally marketed device to which we are claiming equivalence [807.92(a)(3)]: CARBON DIOXIDE-L3K ASSAY (k990754) manufactured by Diagnostic Chemicals Limited, Oxford, CT, USA.

DIAZYME LABORATORIES DIVISION, GENERAL ATOMICS
3550 GENERAL ATOMICS COURT, SAN DIEGO, CA 92121-1194 PO BOX 85608, SAN DIEGO, CA 92186-5608 (858) 455-3000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Roland Strickland
Quality Assurance Manager
Diazyme Laboratories
3550 General Atomics Court
San Diego, CA 92121

JUL 2 1 2006

Re: k060619
Trade/Device Name: Diazyme Carbon Dioxide Enzymatic Assay Kit
Diazyme Carbon Dioxide Control Set
Regulation Number: 21 CFR§862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Code: KHS, JJX
Dated: June 30, 2006
Received: July 7, 2006

Dear Mr. Strickland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

DIAZYME

Indications for Use

510(k) Number: k060619

Device Name: Diazyme Carbon Dioxide Enzymatic Assay Kit
Diazyme Carbon Dioxide Control Set

Indications For Use: Diazyme Carbon Dioxide Enzymatic Assay Kit, in conjunction with Diazyme Carbon Dioxide Calibrator, are intended for the quantitative determination of carbon dioxide (CO_2) in serum and plasma.

Diazyme Carbon Dioxide Enzymatic Assay Kit contains a single-point calibrator. The calibrator, along with 0.9% saline as a zero reference, is used to generate a linear graph that will be used in the calculation of carbon dioxide concentrations in unknown samples.

Diazyme Carbon Dioxide Control Set has controls for normal carbon dioxide level and abnormal carbon dioxide level. The controls are used as reference samples for checking the functionality of the Diazyme Carbon Dioxide Enzymatic Assay.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Posted) k060619

DIAZYME LABORATORIES DIVISION, GENERAL ATOMICS
3550 GENERAL ATOMICS COURT, SAN DIEGO, CA 92121-1194 PO BOX 85608, SAN DIEGO, CA 92186-5608 (858) 455-3000